

AMENDED IN SENATE MAY 24, 2002

AMENDED IN SENATE MAY 14, 2002

**SENATE BILL**

**No. 1401**

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**Introduced by Senator Vincent**

February 13, 2002

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An act to amend Section 1626 of the Health and Safety Code, relating to blood products.

LEGISLATIVE COUNSEL'S DIGEST

SB 1401, as amended, Vincent. Blood products.

Existing law provides for the regulation of the production and use of human whole blood or human whole blood derivatives administered by the State Department of Health Services. A violation of these provisions is a misdemeanor.

Existing law makes it unlawful, with certain exceptions, to use blood obtained from a paid donor in any transfusion of blood. Until January 1, 2003, the use of blood platelets secured from paid donors through the hemapheresis process is excepted from this prohibition if certain requirements are satisfied.

This bill would extend the application of the exception described above indefinitely and would add to the requirements for its applications that the administrator, medical director, or blood bank director of a hospital, with certain exceptions, annually sign and file with the department a declaration regarding the sufficiency of apheresis platelet supplies obtained from volunteer sources.

Existing law requires, until December 31, 2002, blood banks acquiring blood platelets from paid donors to report certain information to the department.

This bill would extend this requirement indefinitely.

By indefinitely extending and revising certain requirements applicable to provisions regulating blood products, a violation of which is a crime, this bill would change the definition of a crime, thereby imposing a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 1626 of the Health and Safety Code is  
2 amended to read:

3 1626. (a) Except as provided in subdivisions (b) and (c), it  
4 shall be unlawful, in any transfusion of blood, to use any blood that  
5 was obtained from a paid donor.

6 (b) Subdivision (a) shall not be applicable to any transfusion of  
7 blood that was obtained from a paid donor if the physician and  
8 surgeon performing the transfusion has determined, taking into  
9 consideration the condition of the patient who is the recipient of  
10 the transfusion, that other blood of a type compatible with the  
11 blood type of the patient cannot reasonably be obtained for the  
12 transfusion.

13 (c) Subdivision (a) shall not apply to blood platelets secured  
14 from paid donors through the hemapheresis process if all of the  
15 following requirements are satisfied:

16 (1) The administrator, medical director, or blood bank director  
17 of the hospital annually signs and files with the department a  
18 declaration stating that, based on the previous year's experience,  
19 due to supply or cost factors or a combination of availability at the  
20 point of care, or both, apheresis platelet supplies obtained from  
21 volunteer sources are expected to be insufficient to meet the  
22 hospital's needs for patient care. A hospital that, by contract, relies  
23 primarily on apheresis platelets obtained from volunteers may  
24 transfuse, on a case-by-case basis, apheresis platelets from paid



1 donors without filing a declaration with the department when the  
2 availability of apheresis platelets from volunteer donors is  
3 insufficient to meet patient needs.

4 (2) The blood platelets are ordered by a doctor holding a valid  
5 California physician's and surgeon's certificate.

6 (3) The blood platelets are secured from a single donor and are  
7 sufficient to constitute a complete platelet transfusion.

8 (4) The donor's identification number is recorded on the  
9 platelet label and is kept in the records of the entity providing the  
10 blood platelets for a minimum of five years.

11 (5) The donor has been examined by a doctor holding a valid  
12 California physician's and surgeon's certificate, and a repeat donor  
13 is reexamined at least annually.

14 (6) The transfusion is performed in a general acute care  
15 hospital.

16 (7) The blood platelets are processed according to standards  
17 issued by the American Association of Blood Banks, pursuant to  
18 Section 1602.1.

19 (8) The donor and blood are tested in accordance with  
20 regulations issued by the department.

21 (9) The entity providing the blood platelets is licensed by the  
22 department.

23 (10) The information that the donor of the blood platelets was  
24 compensated is printed on the label in accordance with Section  
25 1603.5.

26 (11) In all instances, a potential donor shall provide a blood  
27 sample that shall be tested with the standard panel of blood tests  
28 required by the ~~State Department of Health Services~~ *department*  
29 for all blood donations. The results of the testing shall be obtained,  
30 evaluated, and determined to be acceptable prior to allowing the  
31 potential donor to provide his or her first donation of platelets. In  
32 addition, all donors shall be required to schedule an appointment  
33 for platelet donation.

34 (12) Any entity that is not collecting blood platelets from paid  
35 donors on August 1, 2000, shall obtain written permission from the  
36 director prior to compensating any donor for blood platelets.

37 (d) (1) Commencing in January 1996, those blood banks  
38 collecting blood platelets from paid donors shall report all of the  
39 following information to the department:

1 (A) The specific actions undertaken to obtain blood platelets  
2 from volunteer donors.

3 (B) The percentage of compensated and volunteer donors from  
4 whom blood platelets were obtained during the period covered by  
5 the report.

6 (C) The number of repeat donors making platelet donations  
7 during the period covered by the report.

8 (2) The department shall transmit the information received  
9 pursuant to this subdivision to the Senate Health and Human  
10 Services Committee and the Assembly Health Committee for  
11 review by those committees consistent with subdivision (a). The  
12 department shall monitor and assess the supply and distribution of  
13 hemapheresis products, and shall recommend to the Legislature  
14 any action the department believes beneficial to the supply, safety,  
15 and quality of blood products used in this state.

16 (3) Paragraph (1) is not intended to require the disclosure and  
17 reporting of information that would put the blood banks at a  
18 competitive disadvantage in attracting volunteer donors.

19 SEC. 2. No reimbursement is required by this act pursuant to  
20 Section 6 of Article XIII B of the California Constitution because  
21 the only costs that may be incurred by a local agency or school  
22 district will be incurred because this act creates a new crime or  
23 infraction, eliminates a crime or infraction, or changes the penalty  
24 for a crime or infraction, within the meaning of Section 17556 of  
25 the Government Code, or changes the definition of a crime within  
26 the meaning of Section 6 of Article XIII B of the California  
27 Constitution.

